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July 23, 1998

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FEDERAL COMMUNICATIONS COMMISSION
OFFICE OF THE SECRETARY

Ms. Magalie Roman Salas
Secretary
Federal Communications Commission
Room 2222, Mail Stop 1170
1919 M Street, N.W.
Washington, DC 20554

Re: RM- 9157 - *Ex Parte*

ORIGINAL

Dear Ms. Salas:

On July 22, 1998, Steve Goedeke, Director of Communications System Development for Medtronic, Eduardo Villaseca, Senior Principal Engineer Electromagnetic Systems for Medtronic, and I made an *ex parte* presentation to the Wireless Telecommunications Bureau staff listed below Personnel from the Food and Drug Administration also participated in the meeting. In addition to materials submitted previously on June 8 and on July 8 of this year as *ex parte* presentations, we supplied a study prepared by Mr. Villaseca concerning the RF specific absorption rate to be expected for a medical implant device transmitter of the sort contemplated for operation under the proposal. A copy of that study is enclosed. We also encouraged the Commission to move forward with a notice of proposed rule making that would call for the amendment of Part 95 to create the Medical Implant Communications Service to operate in the 402 - 405 MHz MHz band.

Please contact me if there is any question concerning this matter.

Sincerely,

David E. Hilliard

David E. Hilliard
Counsel for Medtronic, Inc.

cc: D'Wanna Terry, Laura Smith, Dr. Tom Stanley, Josh Roland, David Wye, and Eugene Thomson

Enclosure: SAR Study (FDTD for BioelectromagneticsL Modeling MICS Implant in the Human Body)

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List ABCDE

The Medical Implant

Communications System

FDTD for Bioelectromagnetics:

Modeling MICS Implant in the Human Body

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7/11/98

FDTD for Bioelectromagnetics: Modeling MICS Implants in the Human Body

Medtronic is proposing to implant a wireless communication devise (MICS) in a patient's body. It is therefore important to be able to predict the effects and the reliability of such an implant. Bioelectromagnetic models provide the basis for these predictions.

Preliminary models used a mathematical technique called the Method of Moments to model the performance of an implanted device, but the Method of Moments could not predict effects around the entire body: it was limited to predicting performance in a line perpendicular to the body surface, with transmissions moving through only one type of tissue and air.

These initial models were very important in establishing the practicality of MICS, but they need refinement and expansion before they can provide the type and quality of information needed as MICS development proceeds. In particular, we need to be able to see the variation of gain with location around the body, to ensure that MICS will operate reliably, and to evaluate the absorption rate of power into the body while MICS is operating, to ensure that MICS will operate safely.

FDTD Modeling

For this more advanced, improved modeling, we have adopted a new technique, called Finite Difference Time Domain, or FDTD, modeling. FDTD was originally developed by [Yee[1]]and has been described extensively in the literature. The method is a direct solution of the differential form of Faraday's and Ampere's laws. These differential equations are converted into difference equations using the central difference approximations. The field components are interleaved on each unit cell, so that the E and H components are half a cell apart, which is referred to as "leap-frog" scheme. In addition to being leap-frogged in space, they are also leap-frogged in time. The E field is assumed to be at time $n\Delta t$, and the H field is assumed to be at time $(n+1/2)\Delta t$.

The steps in the FDTD solution are:

1) Define model values of ε, ρ and μ at each location.
2) Assume initial conditions (usually that all fields and the sources are zero)
3) For each time step, n
   a) Specify fields at source
   b) Calculate E(n) for all locations
   c) Calculate H(n+1/2) for all locations.
4) Stop when the solution has converged. For transient fields, this means all the fields have died away to zero. For sinusoidal fields, this means that all the fields have converged to a steady-state sinusoidal value.

[1] **Yee, K.S.**, Numerical solution of initial boundary value problems involving Maxwell's equations in isotropic media, *IEEE Trans. Ant. Prop.*,14(3), 302, 1966

FDTD has become the preferred method for bioelectromagnetic calculations at radio frequencies. It is efficient for modeling large-scale heterogeneous penetrable objects — like the human body. FDTD allows the use of many dielectric constants, allowing definition of different types of tissue and organs within the body. The Method of Moments, in contrast, is computationally extremely expensive to use with more than two dielectric constants, severely limiting our ability to define different tissue types. The Method of Moments also makes unreasonably large demands on computer memory and time when modeling internal fields in electrically large lossy dielectric bodies, such as the human body, which FDTD can handle more economically and simply. However, the Method of Moments works excellently with wires and metal patches, which made it the preferred choice for the preliminary MICS analysis.

FDTD has numerous other advantages for more advanced modeling. It is very accurate and fairly easy to use. It operates with a regular, orthogonal grid, with the wave frequencies of the modeling dependent on the dimensions of the grid. In the case of MICS modeling, a 5 mm grid of six million cells allowed creation of a model effective up to 1 gigahertz. Newly available high performance absorbing boundary conditions allow good computations throughout the body without the distortions that occurred in earlier models as a result of reflections from the outer radiation boundaries of the model.

FDTD provides an explicit time advance, with no systems of equations to solve. It can be applied to a wide variety of materials, such as the range of tissues in the human body. It allows for arbitrary incident fields, and is useful for far- and near-field exposure conditions including coupled sources.

The Visible Human Model

MICS modeling started with a human body model obtained from REMCOM, Inc. This model was created from "frozen man" slices from the Visible Human Project, obtained via the Internet and meshed using custom software.

The bioelectromagnetic human body model is a digitized version of a real human body. A donated cadaver was frozen and sliced in 5 mm slices. Each slice was identified for parameters such as muscle, fat, and bone. The results were digitized to create a total numerical model, using a 5 mm cell, for a total of about six million cells. Twelve different types of tissue were identified. Constitutive parameters were assigned based on the original data, and checked and corrected using interactive editing.

Figure 1 shows a demonstration cross section of the human body model.

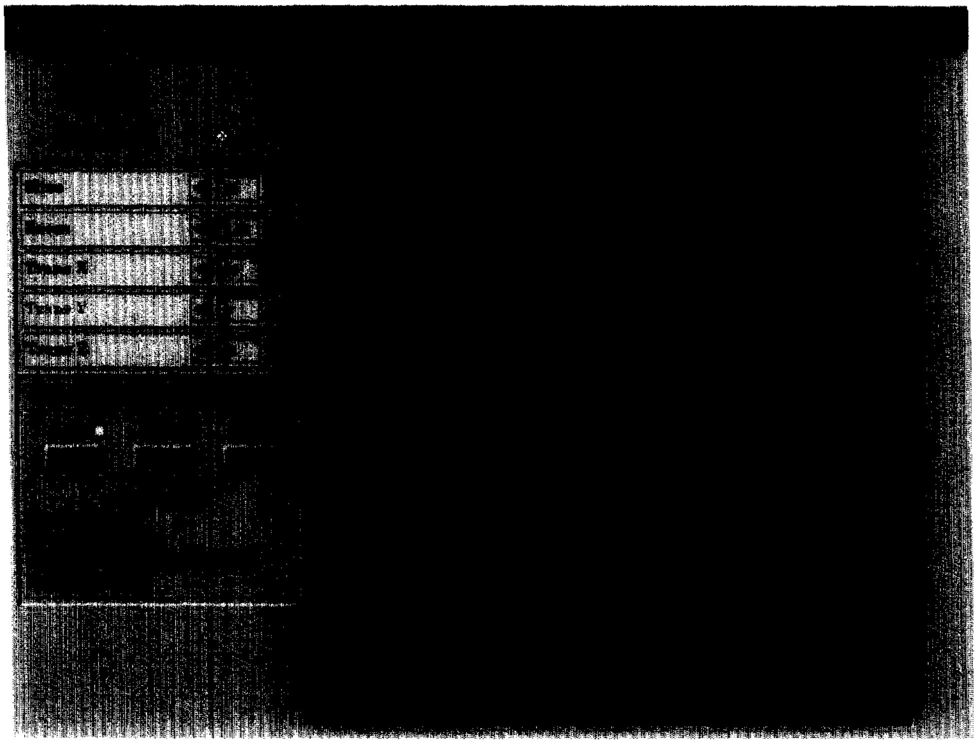


Figure 1. Sample bioelectromagnetic human body cross-section model.

Figure 2 shows an actual section of the human body. Figure 3 shows the corresponding bioelectromagnetic model section. The segmentation of the model and different colors for different types of tissue are clearly visible.

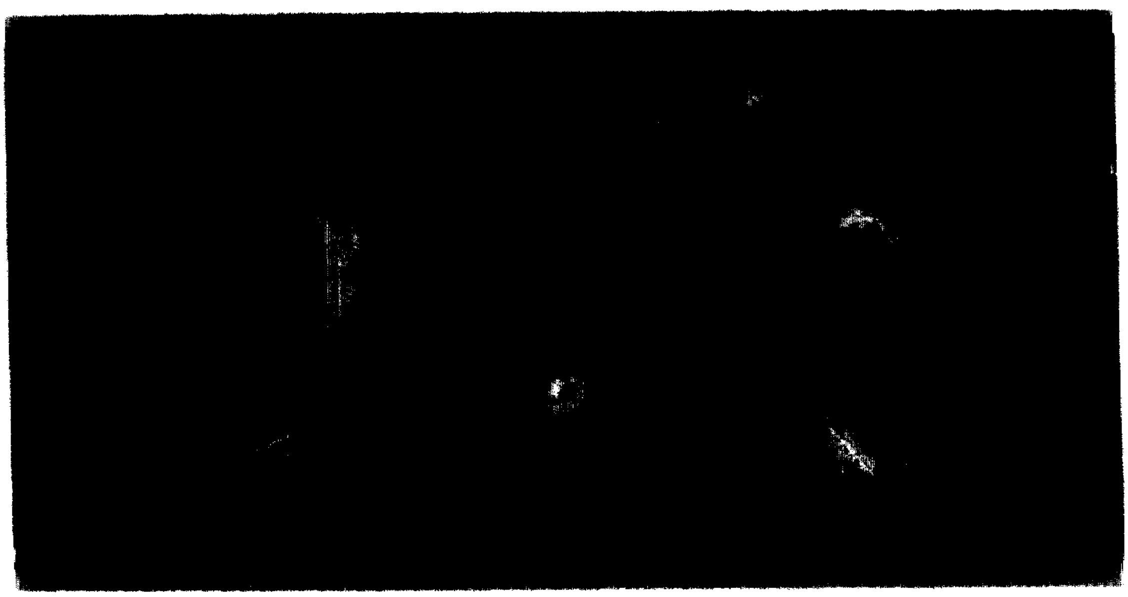


Figure 2. Human body section

Figure 3. Bioelectromagnetic human body model corresponding to the section shown in Figure 2.

MICS Implant

Figure 4 shows the bioelectromagnetic human body model for the chest area where the MICS implant was placed. The implant was placed four cm into the chest below the skin. This also is a new use for the bioelectromagnetic human body model: the first time the model has been used to evaluate an internal implant.

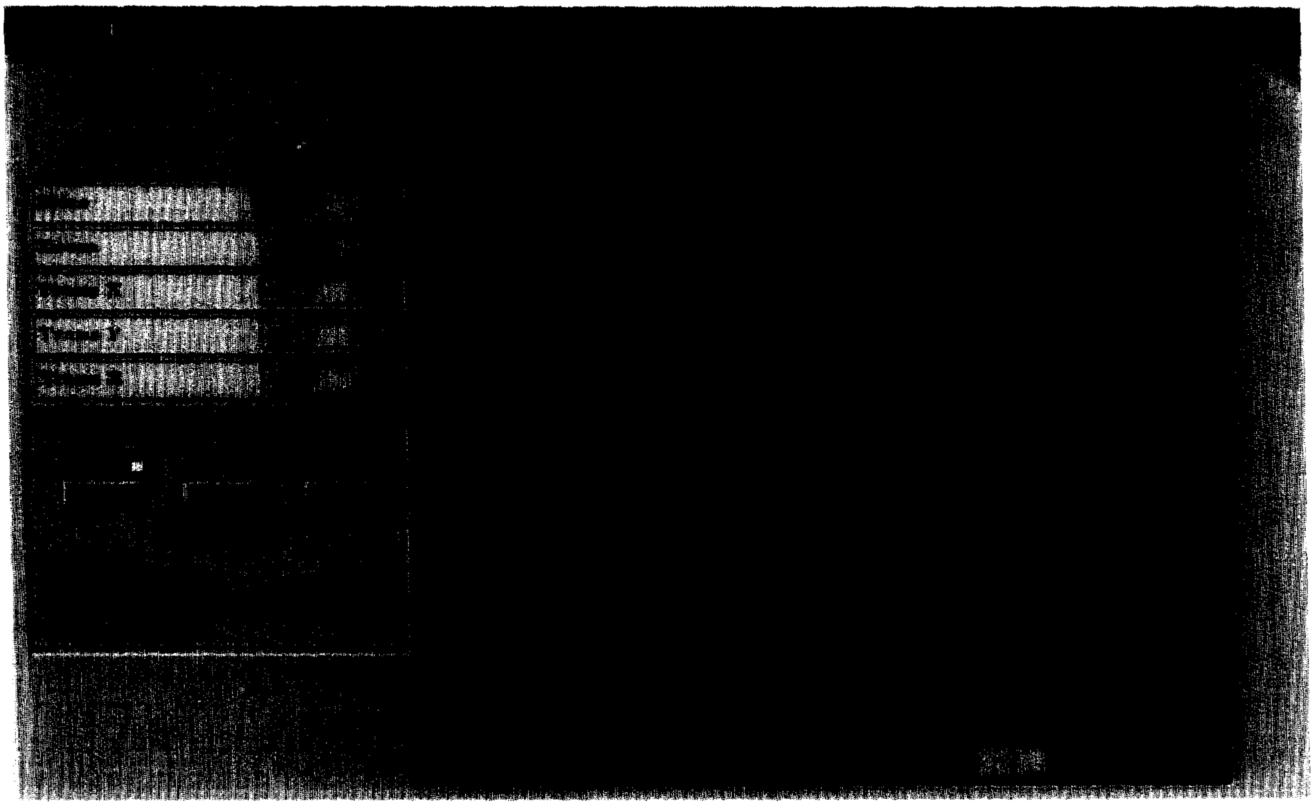


Figure 4. Human body model of chest area

The MICS implant placed in the chest is shown in Figure 5.

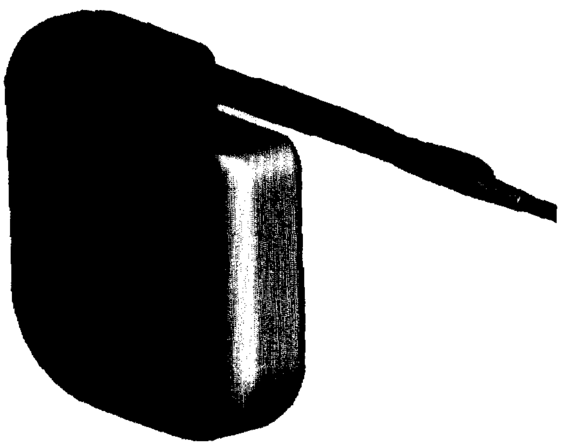


Figure 5. MICS implant with coaxial antenna.

Figure 6 shows the electromagnetic field distribution in the chest area of the body with the MICS implant in place in the upper right quadrant, modeled at 403 MHz.

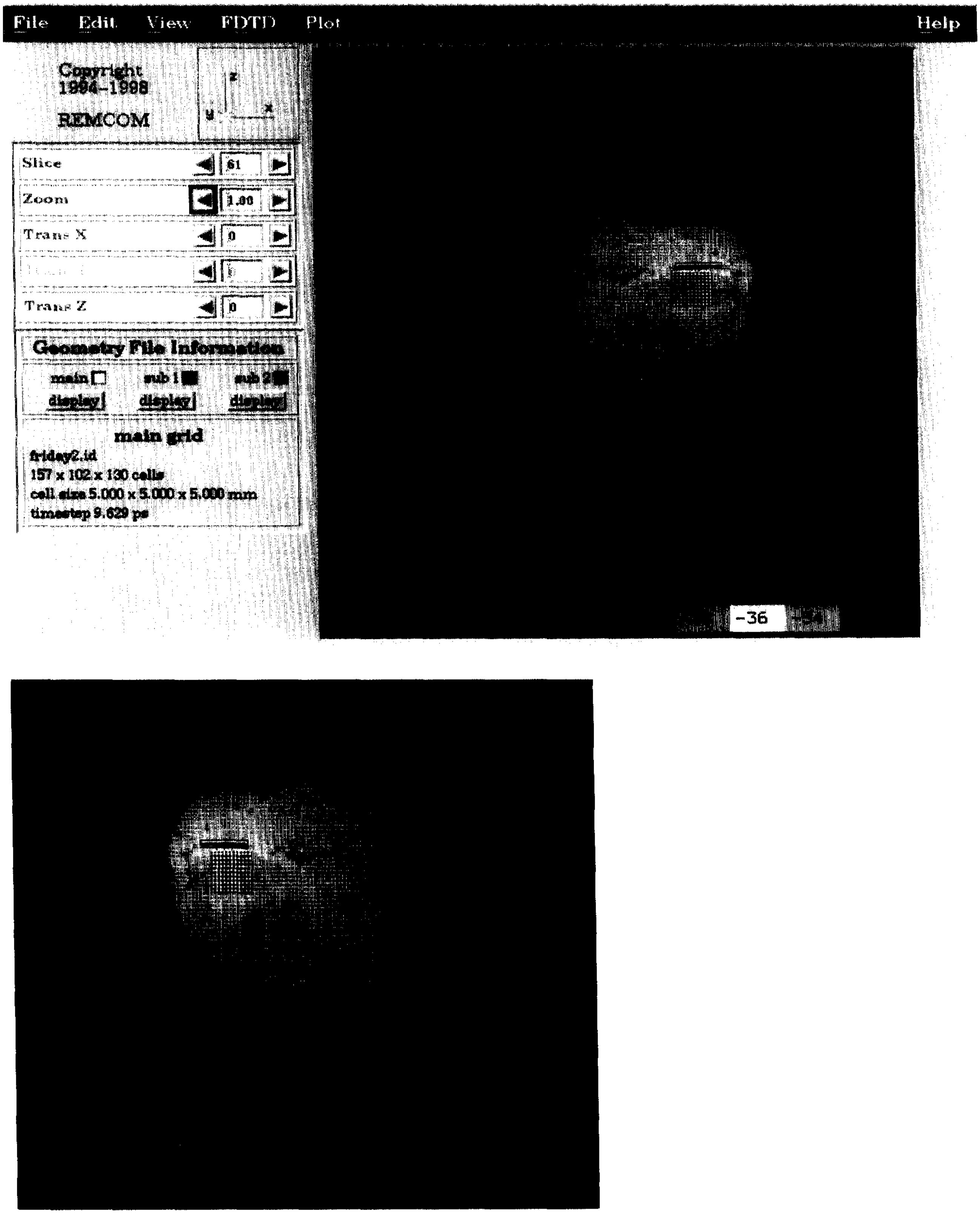


Figure 6. The MICS is visible in the upper left quadrant of the chest in this section.

Figure 7 shows the coverage around the implant, in terms of the azimuth. An azimuth of 90° is directly in front of the body, 0° and 180° are to the sides, and 270° is directly behind the body.

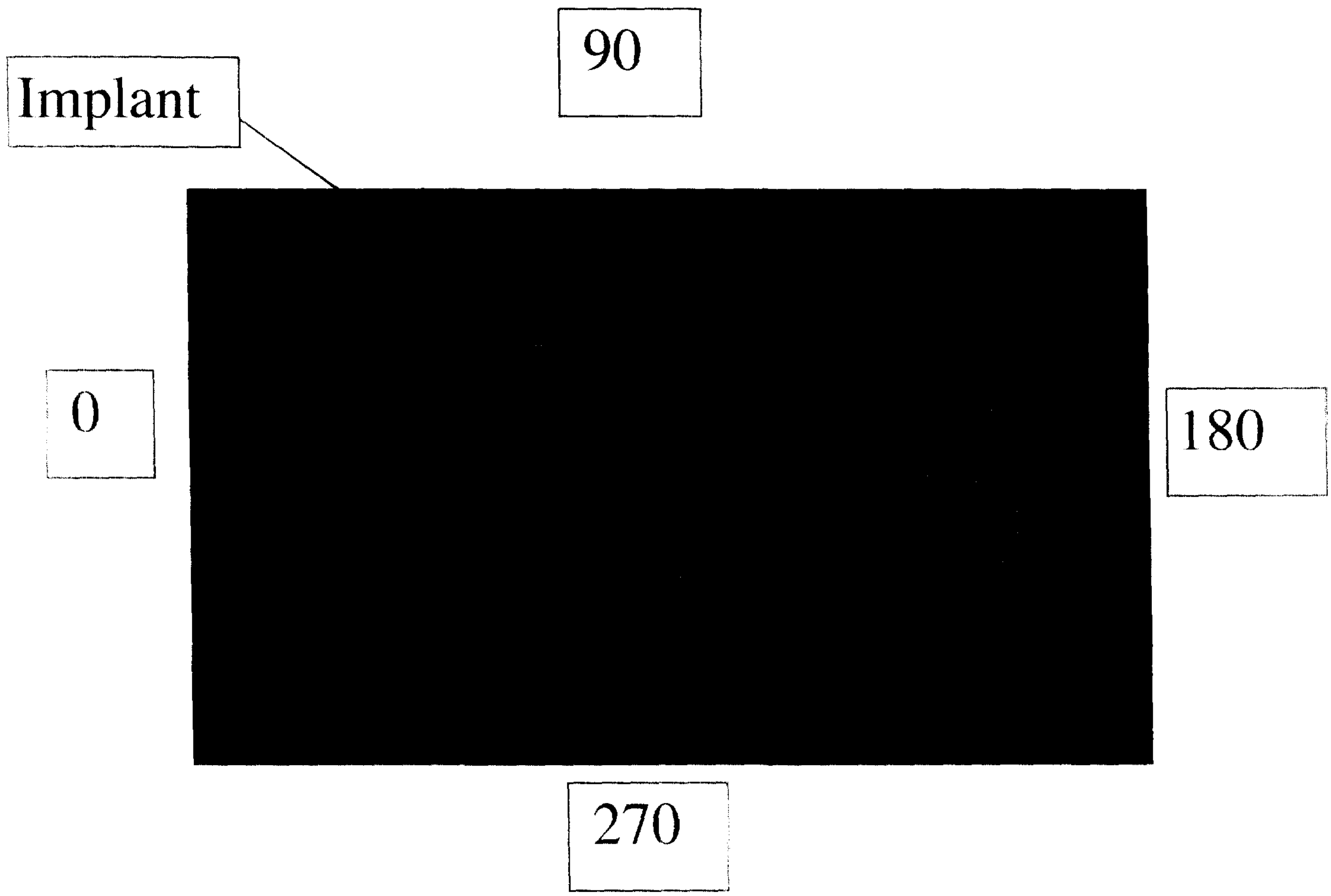


Figure 7. Azimuth coverage of measurements around the MICS implant.

Variation in Gain Around the Human Body Model

Figure 8 shows the results of measuring the implant antenna gain around the body according to the azimuth coverage in Figure 7. The variation of gain with azimuth is clearly visible. The gain varies with the length of the travel path around the body to the receiver; overall, the combination of horizontal and vertical polarization yields a gain that can vary from about –25 to about –40 dBi.

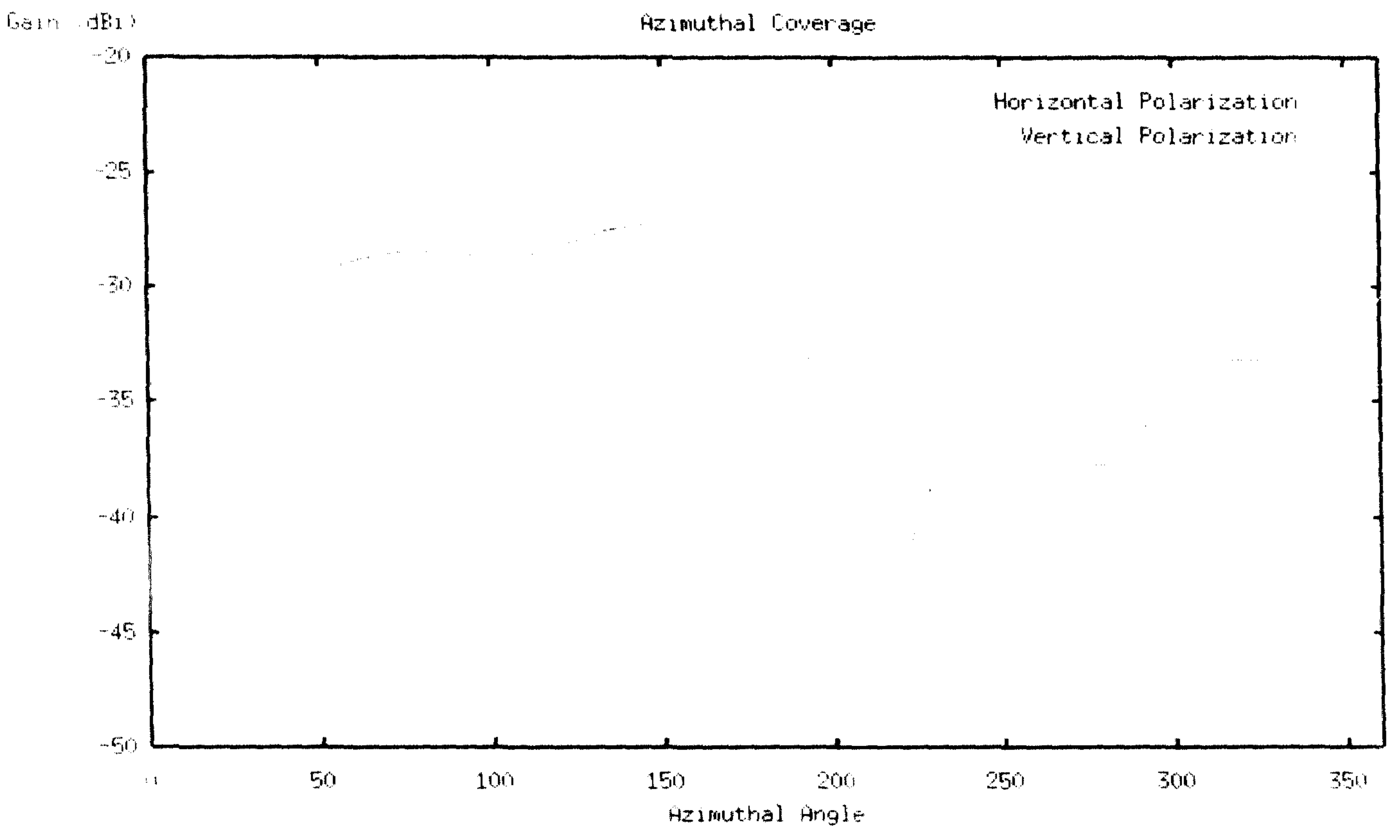


Figure 8. Implant antenna gain as a function of azimuthal angle around the body section shown in Figure 7.

Specific Absorption Rate Modeling

In addition to evaluating MICS performance by modeling the variations in antenna gain around the body, the human body model can be used to evaluate the safety of the MICS implant by examining the Specific Absorption Rate (SAR) in the body. In general, the FDTD method calculates the time-domain vector E and H fields at every location inside and outside of the body. These can be converted to frequency domain fields (magnitude and phase at given frequencies). From them, values commonly of interest in bioelectromagnetic simulations can be calculated, including specific absorption rate, current density, total power absorbed, temperature rise, etc.

SAR is an important measure of the amount of power the implant is putting into the human body per kilogram of tissue. For near-field applications, such as a medical implant with telemetry transmitter, it is important to determine if the device complies with the ANSI/IEEE safety guidelines[ANSI] and newly-mandated FCC guidelines. These guidelines state that an exposure can be considered to be acceptable if it can be shown that it produces SAR's "below 0.08W/kg, as average over the whole body, and spatial peak SAR values not exceeding 1.6 W/kg, as averaged over 1 g of tissue (defined as a tissue volume in the shape of a cube)"[ANSI].

SAR for the MICS implant was evaluated for the Medical Implant Communication System operating at 0 dBm, or power input of 1 milliwatt into the body. The SAR at a given location is given by the following formula:

$$SAR = \frac{\sigma_x}{\rho_x}|E_x|^2 + \frac{\sigma_y}{\rho_y}|E_y|^2 + \frac{\sigma_z}{\rho_z}|E_z|^2$$

where σ is the electrical conductivity and ρ is the mass density at the location of interest.

Figure 9 gives a summary of the results.

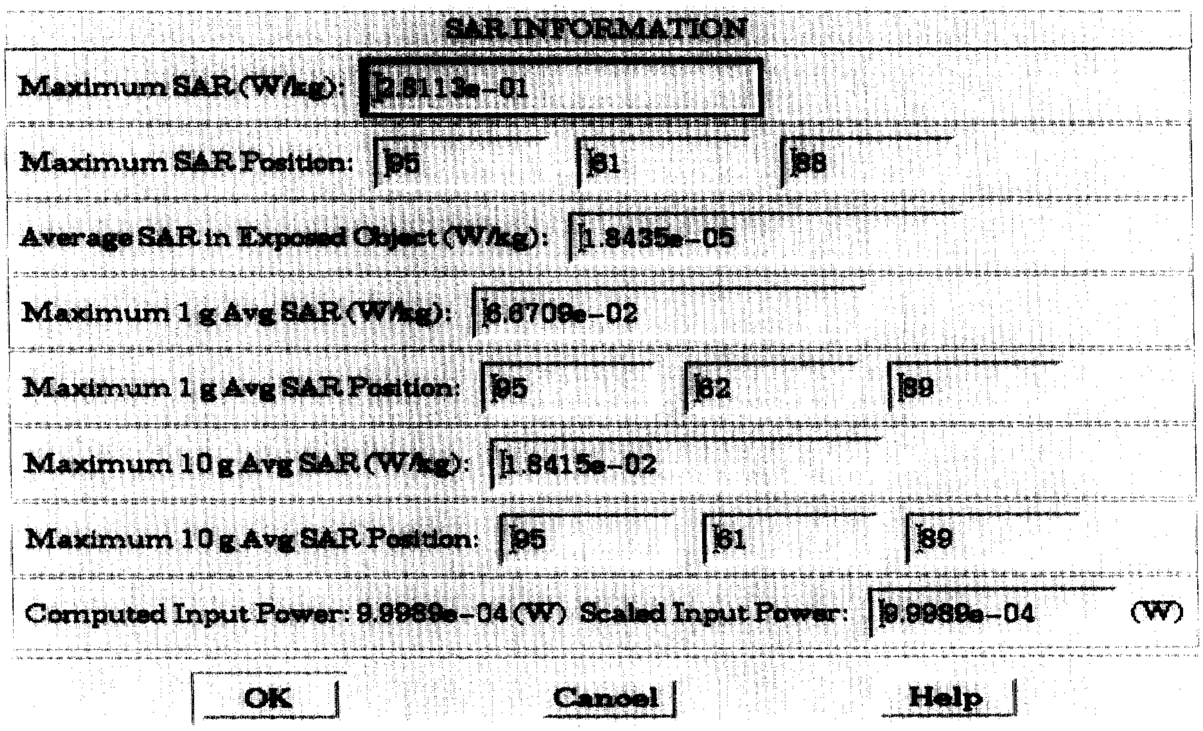
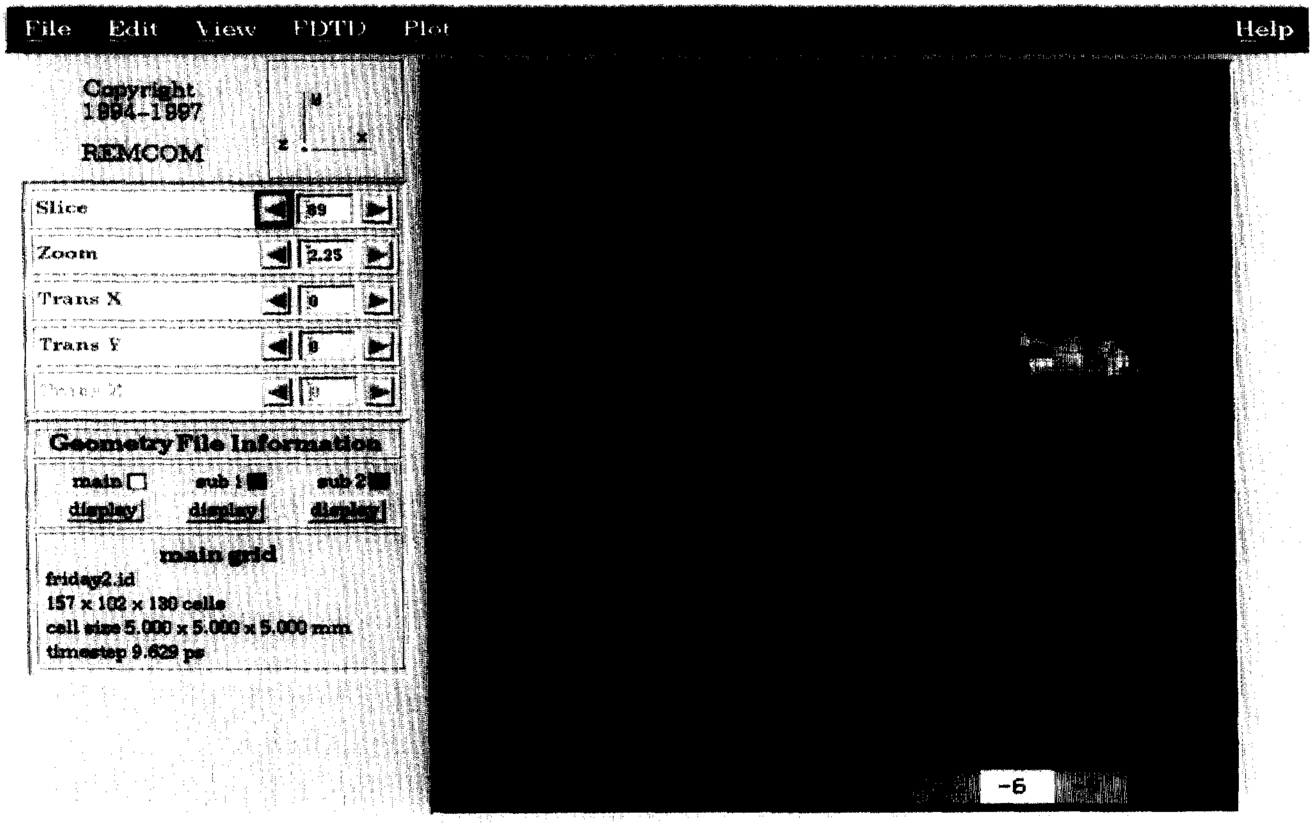


Figure 9. Summary of SAR Information

Three different values must be evaluated to ensure that the implant meets safety standards:

- the maximum SAR considering total power applied to total weight
- the maximum SAR considering the same amount of power applied to 1 gram of tissue
- the maximum SAR considering the same amount of power applied to 10 grams of tissue.

Figure 9 summarized these values and showed the location of the maximum in each case. Figures 10 and 11 illustrate the SAR distribution and maximum for the 1 g average and 10 g average cases respectively.



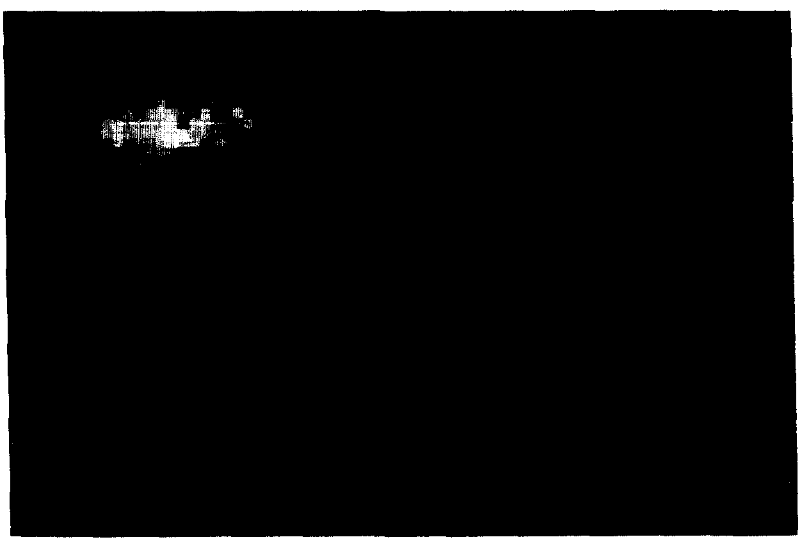


Figure 10. 1 g Average SAR (W/kg). The red dot where the maximum SAR occurs is the location of the connector terminal to the implant.

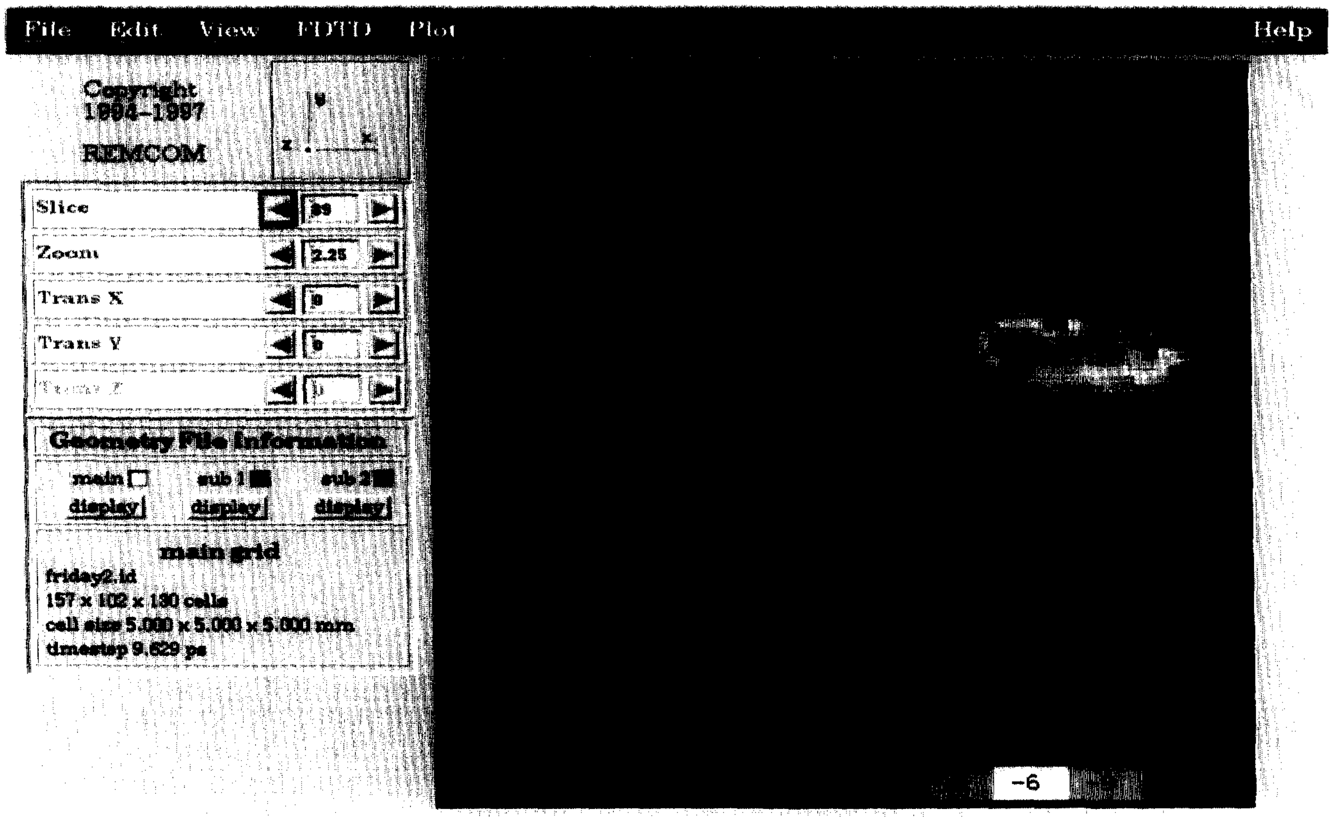


Figure 11. 10 g Average SAR (W/kg). As in Figure 10, the concentration of red marking the maximum SAR is the location of the connector terminal to the implant.

Implant Safety Conclusions

Figures 9 – 11 illustrate the important SAR conclusions:

- The SAR average over the whole body is 1.8e-05 W/kg. This is 36 dB below the ANSI safety standard of 0.08 W/kg.
- The maximum 10 g average SAR is 1.9e-02 W/kg. This is 23 dB below the ANSI safety standard of 4 W/kg.
- The maximum 1 g average SAR is 6.7e-02 W/kg. This is 14 dB below the ANSI safety standard of 1.6 W/kg.

Summary of FDTD Modeling Conclusions

FDTD modeling has been used for the first time with the bioelectromagnetic human body model to obtain implant performance..

The results of modeling implant antenna gain show a variation of gain with location around the body that must be accounted for to ensure that MICS will operate reliably.

Analysis of SAR over the total body, over 1 g of tissue, and over 10 g of tissue reveal an absorption rate of power into the body well within the standard guidelines for safety, demonstrating the ability of MICS to operate safely within the human body.